MICHIGAN ENVIRONMENTAL SCIENCE BOARD

CHILDREN'S STANDARDS INVESTIGATION PANEL
MEETING SUMMARY
MONDAY, FEBRUARY 1, 1999
COURTYARD BY MARRIOTT
7799 CONFERENCE CENTER DRIVE
BRIGHTON, MICHIGAN

PANEL MEMBERS PRESENT
Dr. John A. Gracki, Chair
Dr. George T. Wolff
Dr. Ruth A. Etzel
Dr. Michael DeVito
Dr. Michael A. Kamrin
Dr. William B. Weil
Mr. Keith G. Harrison, Executive Director

MDEQ/OSEP SUPPORT STAFF PRESENT
Mr. Jesse Harrold, Environmental Officer
Ms. Patricia Hiner, Executive Secretary

I. CALL TO ORDER

Dr. John A. Gracki, Chair, called the meeting of the Michigan Environmental Science Board (MESB) Children's Standards Investigation Panel (Panel) to order at 9:00 a.m.

II. INTRODUCTION OF PANEL MEMBERS

Dr. Gracki (Grand Valley State University) indicated that he would be chairing this Panel and that he was a member of the MESB.

Dr. Ruth Etzel (U. S. Food and Drug Administration) stated that she was a pediatrician and an epidemiologist, as well as the Chair of the Committee on Environmental Health for the American Association of Pediatrics.

Dr. William Weil (Professor Emeritus, Michigan State University) introduced himself as a retired pediatrician.

Dr. Michael Kamrin (Institute for Environmental Toxicology, Michigan State University) indicated that he was a toxicologist.

Dr. George Wolff (General Motors Corporation) stated that he was an atmosphere scientist, as well as a member of the MESB.

Mr. Keith Harrison (MESB) introduced himself as an ecologist and the Executive Director of the MESB.

III. EXECUTIVE DIRECTOR UPDATE

Mr. Harrison provided a brief summary of the material that had been submitted to the Panel to date. He indicated that the final Panel member, Dr. Michael Devito (U.S. Environmental Protection Agency toxicologist), would be late. He reminded the audience that the purpose of MESB Panels is to evaluate the science and/or technology of issues presented to it, rather than any particular public policy. He characterized the Panel as data intensive, requiring as much background and supporting data as possible on any scientific opinions. Public opinion would need the same backup to be credible.

Mr. Harrison stated that on October 23, 1998, the Governor sent a letter to the MESB requesting that it examine the environmental standards administered by the Michigan Department of Environmental Quality (MDEQ) in terms of how they relate to children. Specifically requested was a review of the preliminary evaluation developed by the MDEQ last fall regarding the current standards. The MESB was also asked to identify and prioritize the environmental standards that may need to be reevaluated as a result of either outdated or limited scientific data. Also needing to be determined was the type of research necessary to address any of the identified deficiencies. The job of the Panel is not to develop standards. Rather, it is to assist the MDEQ in evaluation of its current standards and identification of any deficiencies that might exist. The Governor has asked that the Panel finish its work by June 30, 1999.

IV. PRESENTATIONS

Mary Lee Hultin (MDEQ Air Quality Division - AQD) stated that toxicologists in the MDEQ are responsible for risk assessment. This is different from risk management, which is handled at higher levels of management or in the legislature. Ms. Hultin reviewed the four steps of risk assessment. These are hazard identification, dose-response assessment, exposure assessment, and risk characterization. For hazard identification and dose-response assessment, the MDEQ relies on published literature. Both human and animal data are located which could identify toxic effects of contaminants. The goal of this research is to identify an appropriate toxicity endpoint for carcinogens and non-carcinogens. A dose-response curve is used to examined what type of response is caused by an increased dose. The AQD is most concerned with inhalation as the route of exposure.

Information that is gathered is rated as to its quality. While high quality human data are preferred, it is often not available and animal data are used for the risk assessment. Factors that influence the quality of animal data include the number of animals used, the adequacy of controls, and the completeness of gross and histopathological exams. The length of the study is also important, with adequate time included to produce the possible results. If there are studies in more than one species, the most sensitive species and/or the most appropriate one to humans is chosen. The target organ or system needs to be identified. If there is more than one target organ or system, the most sensitive is assessed.

Non-carcinogens are treated differently than carcinogens when doing risk assessment.

The goal in risk assessment for non-carcinogens is to estimate the daily lifetime dose to which a person can be exposed without exhibiting any adverse health effects. Efforts are made to find the no observable adverse effect level (NOAEL); however, when this is not possible the lowest observable adverse effect level (LOAEL) is used. These are transformed to a human equivalent dose by the use of uncertainty factors. Standard uncertainty factors are ten-fold for animal to human extrapolation and ten-fold for variance within the population. Other uncertainty factors can also be applied. A ten-fold factor can be applied to subchronic data for extrapolation to a longer term study, and a three- to ten-fold factor can be added if a LOAEL is used in place of a NOAEL. The U.S. Environmental Protection Agency (USEPA) also uses an uncertainty factor or a modifying factor to compensate for a data gap or other deficiency of the study. These uncertainty factors are multiplied; however, it is uncommon for all uncertainty factors to be put together in one risk assessment.

Risk assessment values determined by other agencies, such as the USEPA, are often used by the MDEQ. Also frequently used are reference concentrations or doses published in the Integrated Risk Information System (IRIS). Another source of data is the National Institute of Occupational Safety and Health (NIOSH) which publishes recommended exposure levels.

Although this is not always the case, carcinogens are assumed to have no threshold mechanism of action. Therefore, some level of risk is associated with exposure to a carcinogen and this risk needs to be estimated. Computer models are used to take exposure levels and extrapolate down to zero. The MDEQ currently uses the linearized multistage model. The computer model is used to extrapolate cancer risks from animal data to human data. The shape of the slope factor is taken from the model and the 95 percent upper confidence limit is used. This is adjusted by a scaling factor that relates the surface area of animals to that of humans.

Exposure assessment includes assumptions such as a body weight of 70 kilograms and daily inhalation of 20 cubic meters of air. Other assumptions include a 70-year life span, although 21-year and 30-year exposures are also used. Obviously, these are adult values and not those of a child. Much of the data available deals with exposure by mature animals.

Risk characterization considers what is an acceptable risk. Current policy is that an acceptable risk for carcinogens is one in a million or one in a hundred thousand. This level of acceptable risk is often determined by the legislature. Recent amendments to Part 201 of the Natural Resources and Environmental Protection Act, 1994 PA 451, as amended (NREPA), included a legislatively determined decision that a one in a hundred thousand risk was acceptable for environmental cleanup criteria.

Dr. Weil asked whether there were any plans to make exposure values more realistic for children, who were not only smaller than adults, but also different metabolically. Ms. Hultin replied that there was interest in this at the federal level. While standards proposed by the USEPA are not always applied by the state, federal policy often affects state policy. The MDEQ was also interested in suggestions that the Panel might make. Mr. Harrison clarified that the state might not always follow the lead of the federal

government. This would be especially true if the state standards were more restrictive than the federal standards. This could result from a policy decision to add more factors to account for children in the absence of data. Most federally funded programs do require the states to maintain standards that are at least as stringent as federal standards.

Dr. Kamrin asked whether the uncertainty factor that dealt with population variance, was developed with the awareness that children are more sensitive than adults. Ms. Hultin answered that this was currently a subject of debate and there is a group working with the Food Quality Protection Act to determine whether another ten-fold factor should be applied for children. There is some evidence that extra protection is needed, especially for neonates. Dr. Weil added that much uncertainty came from the fact that even within a class of compounds, there could be a five-fold difference in sensitivity to different compounds. He stated that this additional safety factor should be included unless there is specific data to show that it is not needed.

Dr. Kamrin asked for clarification on the NOAEL, and whether exposures above that level were expected to produce adverse effects. Ms. Hultin responded that this would have to be evaluated for specific compounds. Safety margins are included, but the extent of those would depend on the assumptions included in the risk assessment.

Dr. Weil questioned whether the non-carcinogens were evaluated based on the lifetime average daily dose. Ms. Hultin answered that the lifetime average daily dose was used for carcinogens. For non-carcinogens, there could be a one-year, or a one-hour, or a 24-hour standard. In general, the exposures are assumed to be protective for the lifetime, or the duration of exposure. Dr. Weil stated that his concern was that there were certain ages where exposures were more critical. He noted the current rapid rise in asthma that is probably environmental. It could be due to exposure during a sensitive period at levels that would have little impact later, or over a lifetime.

Mr. Dennis Bush (Surface Water Quality Division, MDEQ) spoke on the relationship of federal and state regulations to criteria development. The 1990 amendments to the Clean Water Act required the USEPA to publish guidance for the Great Lakes System. This guidance included a methodology that the states could use to derive criteria protective of human health and wildlife and aquatic life. It also provided human health criteria for protection from cancer effects for 11 chemicals and from non-cancer effects for 15 chemicals. Another federal statute is the Biosolids Regulation, which sets health-based standards for the disposal and use of sewage sludge.

There are two important state regulations, NREPA Parts 4 and 8 Rules. Part 4 Rules are water quality standards that adopted the USEPA methodology and criteria developed for the Great Lakes Initiative. Part 8 Rules discuss how the criteria are used to develop discharge limits, and include details on things such as using additivity and toxic equivalency factors, and compliance schedules.

The first step in criteria development is determination of an acceptable daily exposure. This is an estimate of the maximum daily dose of a substance that is not expected to result in adverse, non-cancer effects to the general population, including sensitive

subgroups. This is calculated by dividing the NOAEL or the LOAEL by an uncertainty factor. An important source of data for these calculations is the IRIS database. There are minimum database requirements for derivation of a NOAEL or a LOAEL. A tier 1 value is derived from a well-conducted epidemiological study that lasts for at least 10 percent of the test animal's lifespan. For a tier 2 value, there must be a well-conducted short-term study of at least 28 days duration. With a tier 2 value, there are less data and more uncertainty factors would likely be used. If it is not possible to derive either a tier 1 or a tier 2 value, a screening level would be derived. This can include relationships of structure and activity, as well as LD_{50} values. An acute to chronic application factor is applied as well as various uncertainty factors. Total uncertainty factors are mandated to not exceed 10,000 for a tier 1 value, or 30,000 for a tier 2 value.

Exposure assumptions include two liters per day of drinking water, or 0.01 liters per day for recreational exposure only. Fish consumption is assumed to be 15 grams per day. There is a relative source contribution, which is 0.8. This assumes that 80 percent of the exposure to the chemical of concern is through these routes of exposure. Toxic equivalency factors are used for chlorinated dioxins and furans, and additivity is used for both cancer and non-cancer effects. Effluent containing two or more non-carcinogens that produce the same adverse effects through the same mechanism of action may be assumed to be additive. The total incremental risk for effluents containing carcinogens, which produce the same type of cancer through the same mechanism of action, should not exceed 1×10^{-4} and the risk for individual carcinogens should not exceed 1×10^{-5}.

One way in which children are currently protected is that a developmental study will be used if it finds that developmental effects are the most sensitive endpoint. An example of this is mercury, which causes developmental effects. Here, the exposure of pregnant women is of concern and an assumed body weight of 65 kilograms is used.

Ms. Christine Flaga (Toxicology Unit, Environmental Response Division, MDEQ) provided information on Part 201 of the NREPA, which addresses environmental remediation, and specifically, Section 20a, which deals with cleanup criteria. These criteria are based on land use categories, including commercial, industrial, and residential. Generic cleanup criteria have been developed using standard exposure assumptions. Because these criteria are believed to be protective and conservative, no land use restrictions are applied. An alternative is limited remediation where public health is protected through some type of exposure control or engineering control. This could be a containment system or other type of barrier to prevent exposure. This would be used where onsite levels are in excess of the generic cleanup criteria, and requires a restrictive covenant filed with the deed. There is also site-specific remedial action. This would be based on specific exposure assumptions that are unique to the site. Because this is a type of limited closure, a legally enforceable agreement is required. The last option is a facility-specific generic action plan, or a closure, which is usually developed with site-specific soil parameters.

The Part 201 of the NREPA criteria are used by the MDEQ Storage Tank Division as its Part 213 NREPA cleanup criteria, and as screening levels by the Drinking Water and

Radiologic Protection Division. The same criteria are also used by the Waste Management Division for remedial actions within its programs. Within the Environmental Response Division, these criteria are used in several ways, including remedial action plans, fulfillment of due care responsibilities, and making facility determinations. Any property that has groundwater or soil concentrations in excess of generic residential cleanup criteria is considered a facility, and must comply with the NREPA Part 201 requirements. For each set of cleanup criteria there is a technical support document available.

There are four sets of generic groundwater criteria. The first is drinking water criteria. State drinking water standards are adopted when available, unless there is a more restrictive aesthetic criterion. Next are groundwater surface water interface (GSI) criteria. The GSI criteria are Rule 57 values developed by the Surface Water Quality Division as its NREPA Part 4 water quality standards. Third, is the groundwater volatilization to indoor air inhalation criteria. Volatilization of groundwater occurs when volatile chemicals present in groundwater migrate through the soil and basement foundations into indoor air. Finally, there are groundwater contact criteria that protect people who may come into contact with collected groundwater. Other screening levels for groundwater that are not part of NREPA Part 201 criteria include flammability and explosivity, acute inhalation screening, and the solubility of hazardous substances.

NREPA Part 201 soil criteria include those which address the leaching potential of contaminants in the soil. There are soil volatilization to indoor air inhalation criteria, which are similar to criteria for groundwater. There are volatile and particulate soil inhalation criteria to protect the ambient air above contaminated soil, and there are direct contact criteria that address dermal contact with soil. Finally, there are soil saturation screening levels that address the potential concentrations of contaminants in the soil.

The risk assessment methodology used to generate the NREPA Part 201 criteria follow the general MDEQ approach. However a target hazard quotient of one is specified for non-carcinogens. This hazard quotient is the ratio of the exposure level to the referenced, acceptable daily long-term dose. For carcinogens, the target risk is identified as one in a hundred thousand. The generic NREPA Part 201 criteria primarily address single chemicals and individual pathways. However, some chemicals such as polychlorinated bipenyls and the chlorinated dioxins are handled as a group. There is also flexibility within Part 201 of the NREPA program to incorporate additivity, or other demonstrated interactions into risk assessment and the development of cleanup criteria. While a relative source contribution factor is used for drinking water criteria, background exposures are not considered. Most of the chemicals of concern have very limited data available. Lead is an exception, and the information available on its toxicity allows for unique risk assessment procedures.

The USEPA has developed the integrated exposure and uptake biokinetics model that allows incorporation of exposures above and beyond the exposure of the medium of concern. This model, which is specific to children, was used to develop the residential cleanup criteria for soil. The generic exposure assumptions are believed to represent the reasonable maximum exposures and are mainly based on adults. However, the

direct contact criterion does factor in children in that a weighted, age-adjusted exposure is used. When child related or developmental data are available, it can be used. There are about 23 substances on the NREPA Part 201 list whose criteria were developed based on developmental effects. These include lithium, boron, and lead.

A unique situation was highlighted by E.J. Calabrese and others in 1997, when he studied the acute ingestion of large amounts of soil by children. The current generic criteria for chronic exposure assumes a daily soil ingestion rate of 200 milligrams (mg). Children can ingest greater amounts of soil. In the study, they looked at 13 chemicals, four of which were present in doses equal to or greater than human lethal doses. Other contaminants were in the range of nonlethal, toxic effects.

Dr. Kamrin asked what assumptions had been made about the bioavailability of the chemicals studied by Calabrese. Ms. Flaga replied that she would take another look at the article and get back to the Panel. Dr. Kamrin also asked how the USEPA would evaluate a hazardous waste site in the absence of criteria such as Part 201 of the NREPA. Ms. Flaga replied that the USEPA had similar criteria, but they were not official standards.

Dr. Weil asked how the hazard quotient had been calculated. Ms. Flaga answered that this was a long-term average of 30 years for the residential scenario and 21 years for the occupational scenario. She agreed that for a short period, like a day or a month, one could be well over the hazard quotient. Ingestion of dirt by children would happen more in the summer. Eating dirt could be, but is not necessarily, associated with the condition pica. Dr. Weil pointed out that one-half cup of dirt is equivalent to 120 grams. Dr. Weil questioned whether the methodology in the lead studies was able to detect children with lead levels under 15 micrograms (μg) per deciliter. Ms. Flaga answered that the model identified an acceptable blood lead level of 10 μg per deciliter, which was now the target protective level.

Dr. DeVito asked how the age-weighted averages were calculated for the exposure assessments. Ms. Flaga responded that the child portion of the equation involved ages one through six. It was a time-weighted average over the six year period, considered separately from other ages. Dr. DeVito concurred that this was probably the age of greatest exposure. Dr. Kamrin asked if exposure criteria assumed that the exposure occurred directly onsite, rather than nearby. Ms. Flaga said that while ambient air criteria were developed to protect people on site, it also considered those who were off site.

Dr. Deborah MacKenzie-Taylor (Waste Management Division, MDEQ) discussed how risk assessment was used in hazardous waste management. NREPA Part 201 criteria, established in 1995, are still in the process of being incorporated into division programs. The purpose of the Division's hazardous waste management program is to protect human health in the environment by managing the transportation, storage, treatment and disposal of waste that typically shows hazardous properties. It regulates generator accumulation and provides for permitting and licensing of treatment, storage and disposal facilities. The Part 111 of the NREPA gives regulatory authority for this program. Federal authorization is given by the Resource Conservation and Recovery

Act (RCRA), Subtitle C.

Risk assessment is used in the characterization of waste. Characteristics include ignitability, proclivity, and reactivity as well as toxicity. Listed wastes are listed either for one of those characteristics or for an acute hazard. Federal waste codes are used; however, there are additional waste codes that are state specific. As this program is federally funded, state codes can be more stringent, but not less stringent, than the federal codes. The state specific characteristic adds severely toxic as an additional characteristic waste to cover compounds such as polychlorinated dioxins. There are also some state specific listed wastes that are included due to their toxicity.

The regulatory authority for the Division's solid waste management program is Part 115 of the NREPA. There is also federal authorization by RCRA, Subtitle D. This program oversees the management and disposal of non-hazardous solid waste and solid waste landfills, and provides permitting and licensing authority for solid waste landfills. It also provides for the beneficial reuse of solid wastes that meet risk-based standards designed to protect human health and the environment. Risk assessment is also used for remedial actions and cleanup of accidental releases.

There is also the groundwater program that is regulated according to Part 31 of the NREPA. The purpose of this program is to protect public health and welfare by maintaining the quality of groundwater in all usable aquifers for individual, public, industrial and agricultural water supplies. This is done by careful authorization of waste water discharge to the ground or groundwater. Rules for this are currently being revised in order to better clarify the limits contained in the regulations. Some specific standards in the rules include concentration limits on total inorganic nitrogen, sodium, chloride, and other substances. There are also treatment-based standards that focus on the toxicity component. In addition, there are risk-based standards related to NREPA Part 201 residential criteria.

There are several ways that the Waste Management Division is protective of children's health. Data on developmental toxicity is used when available. Examples of this are the chemicals boron, lithium, and lead. Another area of increased protection deals with total inorganic nitrogen for groundwater discharges. Nitrates and nitrites are of concern for hemoglobinemia in infants, causing the blue baby syndrome. Current drinking water standards are 10 mg nitrate per liter and one mg nitrite per liter. In order to be more protective, five mg per liter total inorganic nitrogen was chosen as the standard because ammonia can be converted to nitrate once it is discharged, and the allowable nitrite level was set at 0.5 mg per liter.

Additional risk considerations include the possibility of indirect pathways and the exchange of contaminants between soil, air, and water. Cumulative risk is determined using individual exposure pathways unless there is a specific case for interactions. Part 111 of the NREPA may require evaluation of total exposure from all site-specific exposure pathways. Additive risk is defined for only specific chemicals, or on a case-by-case basis. However, Part 111 of the NREPA may require a total cancer risk for all chemicals and a hazard quotient for chemicals with the same target organ.

Dr. DeVito noted that several of the presentations had mentioned boron and lithium. He asked what was the source. Dr. MacKenzie-Taylor replied that boron can be found in solid waste landfills in fairly high concentrations. Fly ash disposal sites can be a source of groundwater contamination by both lithium and boron. These are very mobile compounds. Although it has been specifically looked for, mercury is rarely seen as a concern for release to groundwater or soil.

Dr. Weil asked if there was a map available that showed the location of hazardous facilities. Dr. MacKenzie-Taylor responded that the Michigan Resource Information System (MIRIS) would be a good source. While it might not show all the underground storage sites, the MIRIS map did have hazardous waste treatment, storage and disposal facilities entered. Dr. Weil said that he would be interested to see if there was a correlation between hazardous sites and increased incidence of illness in children.

Mary Lee Hultin spoke about the role of the AQD, which deals with state air quality regulations, including Michigan air toxics rules, as well as the federal Clean Air Act and National Ambient Air Quality Standards (NAAQS). The Michigan air toxics rules were first promulgated in April 1992, and amended November 1998. These rules apply to all new and modified processes that are required to get a permit to install, that emit a toxic air contaminant. A toxic air contaminant is defined as any air contaminant that is or may become harmful to the public or the environment. There are 40 substances listed which are exclusions, including the six NAAQS, low toxicity compounds and some simple asphyxiants.

The AQD uses three types of screening levels or criteria. The first is an initial threshold screening level (ITSL) which looks for threshold, generally non-cancer, effects. These levels have been set for some carcinogens when a threshold mechanism of action has been clearly demonstrated. There is a hierarchy of methods to develop an ITSL, which rates the quality of data involved. There is also a 0.1 μg per cubic meter default screening level if there is no toxicity data on a compound that exhibits a threshold mechanism of action. This is based on LD_{50} and LC_{50} data, using statistical calculations, and is less stringent than the previous default level due to more current data.

Initial risk screening levels are used for compounds that have a non-threshold mechanism of action. In general, these are carcinogens. This level is set at one in one million and applies to chemicals that are being emitted from the process that is being permitted. The methodology is covered under Rule 231. There is also a secondary risk screening level. This is an option for facilities that may not be able to meet initial risk screening levels. The secondary level represents a risk of one in a hundred thousand, but covers all processes at the source facility.

Compliance with screening levels is determined using either direct emission data, dispersion models, or screening methods such as a dilution factor matrix. Screening levels are associated with averaging times of one hour, eight hours, 24 hours, or one year. The one-hour averaging times are more stringent and are applied for compounds such as those with an irritant potential. The permits also state maximum hourly

emission rates allowed. This will give protection against short-term peaks even for compounds with long averaging times.

There are some exemptions from the screening levels allowed if it is demonstrated that the emissions will not cause injurious effects to human health or the environment. Alternate methods for determining screening levels are considered when they are supported by strong scientific data. Chemical interactions are also considered, including additivity, synergism, and antagonism. This is not routine, but is done for certain compounds such as ethers and petroleum distillates. Indirect exposure routes can also be considered for specific permits, such as hazardous waste incinerators. If necessary, the AQD can convene a scientific advisory committee to provide recommendations. This has not been done since the 1998 amendments.

Ms. Hultin also addressed federal regulation of air quality. She stated that toxic air pollutants were first addressed in the 1970 Clean Air Act (CAA), which set standards for ozone, carbon monoxide, lead, particulate matter, sulfur dioxide and oxides of nitrogen. In addition, Section 121 specified the establishment of National Emission Standards for Hazardous Air Pollutants (NESHAPs). The 1990 amendments to the CAA listed 188 hazardous air pollutants (HAPs) in Section 112, and categorized the sources of these HAPs. A major source was considered to be one that emits at least 10 tons per year of any HAP or 25 tons per year of all HAPs combined. These major sources are subject to maximum available control technology (MACT). Area sources are any source, such as a dry cleaning facility, which is not a major source. These are subject to a lesser standard of control called generally available control technology (GACT).

The USEPA is currently working on a residual risk program. Health-based standards, required within eight years after promulgation of control technology standards, are now in draft form. These are designed to protect public health with an ample margin of safety and prevent adverse environmental effects while considering costs, energy and safety. These standards will apply only to major sources of the 188 HAPs.

Other programs in Section 112 include the urban air toxics program, prevention of accidental releases and the Great Waters Program that covers atmospheric deposition in the five Great Lakes, Chesapeake Bay, Lake Champlain, and coastal waters. The AQD has had various interactions with these federal programs, providing information and education for the 112R program. The AQD has reviewed the residual risk report and the Great Waters report, providing input for these documents. There is also interaction with the permit section and other areas that deal with compliance with national standards. One way in which the national standards differ from those of the state is that the national standards deal with ambient impacts, while the state standards only consider the emissions from a particular permitted facility.

Dr. Kamrin asked for clarification on the definition of low toxicity compounds, which were excluded as toxic air contaminants. Ms. Hultin replied that these were fairly inert substances, such as nuisance particulates or argon gas. Dr. Kamrin also asked which carcinogens were classified as threshold carcinogens. Ms. Hultin responded that she

thought magnesium silicate and terbutyl alcohol were included; however, she would review this and subsequently provide the Panel with details.

Dr. Weil asked where the particulate matter in air originates. Ms. Hultin indicated that it originates from a variety of sources. The regulation of particulate matter is based on the NAAQS. When a permit applicant has a compound of such low toxicity that it would only cause a problem if it exceeded the particulate standard, these standards are specified in the permit. As stated in the NAAQS, particulates of most concern are those of 2.5 μm or less in diameter.

Ms. Hultin also spoke about work done by the Children's Health Protection Advisory Committee (CHPAC). This committee was formed of outside experts to advise the Office of Children's Health Protection and the USEPA. The CHPAC recommended a reevaluation of the NESHAP for chloralkali plants, to provide better protection from mercury. The USEPA agreed and has included this issue in their multimedia strategy for persistent accumulative and toxic pollutants. Protection from the effects of mercury includes fish intake advisories. The USEPA is considering body weight criteria that more accurately reflect the exposures of children and women of child-bearing age.

Another issue selected by the CHPAC is protection from pesticides, with the recommendation that more accurate children's exposure factors be considered. The USEPA is currently planning to collect data on pesticide exposures by working with the National Institute of Occupational Safety and Health on pesticide case-reporting projects. Triazine pesticides are the first tier of pesticides to be reevaluated for compliance with the Food Quality Protection Act, and the CHPAC has recommended reevaluation of the atrazine drinking water maximum contaminant level.

The CHPAC also recommended reevaluating insecticide tolerance for methyl parathion, dimethoate, and chlorpyrifos. Because the nervous system of children continues to develop until puberty, it is particularly vulnerable to the effects of neurotoxicants. Of the 39 pesticides registered for use on food, these three represent the bulk of dietary risk. The USEPA is presently working on a methodology to assess cumulative risks posed by organophosphates, including specifically the risk to children.

Asthma was another area in which the CHPAC made recommendations, recognizing the important role of indoor air in the aggravation and development of childhood asthma. A holistic view of outdoor and indoor air quality was emphasized, rather than the identification of a single standard. The USEPA has recognized that since 1990 asthma has increased 160 percent in children less than five years of age. They have funded eight centers for children's environmental health and prevention research. Five of these centers are specifically focused on asthma, with assessments on the role of indoor allergens on the induction and exacerbation of asthma. Ms. Hultin mentioned that she was a member of the newly formed Michigan Asthma Steering Committee. The committee is funded by a grant from the Michigan Department of Community Health. It will be making recommendations for dealing with asthma in Michigan.

Dr. Kamrin stated that the official USEPA definition of a reference dose was an estimate of a daily exposure that is likely to be without appreciable risk with deleterious effects during a lifetime. He asked how the likelihood of appreciable risk was quantified. Ms. Hultin said that she thought it was designated as within an order of magnitude. Dr. DeVito clarified that the dose and not the risk was measured within an order of magnitude. Above a certain level, some risk was assumed but it was not quantified.

Dr. Weil commented that the intraspecies factor of ten assumed variations in sensitivity among the adult population, and was not designed to account for children. If children are assumed to be at greater risk than adults, then an additional safety factor must be added. Dr. DeVito added that if the endpoint had been based on a developmental study, only the intraspecies factor of ten would be needed. However, there were not many developmental studies available, to demonstrate the effects on children. Dr. Kamrin noted that some people in the USEPA believe that children are already adequately included in the range of sensitivity specified by the intraspecies factor.

V. PUBLIC COMMENT

Genese Smith Watkins (Michigan Chemical Council) asked whether the Panel would also consider other items such as lifestyle and prenatal care as risk factors. Mr. Harrison answered that it would depend on whether it was found that such factors had a direct bearing on the development of the administered standards of the MDEQ.

Tracy Easthope (Ecology Center) stated that she represented a number of groups with environmental interests who would be following the work of this Panel very closely. Ms. Easthope asked what percentage of the chemicals, which showed developmental toxicity, had documented *in utero* exposure. Ms. Flaga said that she would get that information to Ms. Easthope. Ms. Easthope then questioned the manner in which new data was accessed in determining exposure levels. Ms. Flaga stated that in the AQS toxicity updates were done every three years. Records of the literature searches conducted are maintained. Ms. Easthope also asked for an explanation of the decision not to regularly consider background exposures. Ms. Flaga answered that this was a policy decision, and an attempt to make the criteria more reasonable.

Ms. Easthope mentioned the cumulative exposure project that had been conducted by the USEPA. She asked what had been the state response to the findings. Mr. Bob Sills (AQD) responded that the cumulative exposure project had been designed as an exercise to be a proxy for lacking ambient monitoring data. The results showed a great number of compounds exceeding a one in a million cancer risk throughout the U.S. However, this was based on 1990 emissions data, and it has not been fully supported by ambient or other monitoring data. It could still be a very useful tool to focus efforts. The data specific to Michigan are currently being evaluated, but there are places noted that show excess levels of carcinogens and non-carcinogens.

VI. PANEL DISCUSSION

Dr. Kamrin indicated that the Panel stick as closely as possible to science issues in its deliberations. He stated that it would be difficult to address the issue of protectiveness as this was a concept that was not well defined scientifically. Dr. Kamrin said that he would like to avoid becoming involved with risk management issues, where decisions were based on policy, such as adding a factor of ten to all chemicals. The best science would involve a process whereby each chemical was examined individually. Dr. Weil responded that there were a million chemicals in the environment and close to several hundred commonly used pesticides. There was limited toxicity data, with very little data specific to children. Research on each chemical would not be feasible. Dr. Weil stated that it was important to consider the documented increases in childhood illnesses of the past two decades. These might have an environmental basis, and a regulatory approach needs to consider how best to protect children in the absence of complete data.

Dr. Gracki noted that the charge to the Panel was to review the report already prepared by the MDEQ, and identify standards that should be reevaluated and areas that need further research. Dr. Weil said that the Panel should state which regulations needed modification and how they needed to be modified. This is partially a policy matter. Mr. Harrison noted that any regulation has a scientific component as well as a policy component, which can sometimes be an interpretation of the scientific data. He added that each of the Panel members had a different perspective, and getting input from these various perspectives was the reason for bringing everyone together. The focus, however, does need to be on an evaluation of the available science and the identification of those areas where the science is either weak or lacking altogether.

Dr. Wolff stated that the medical experts on the Panel would be valuable in pointing out any gaps in the preliminary MDEQ evaluation. He affirmed his hope that current risk assessments were being done to protect the most sensitive populations. He gave the example of ozone, where outdoor children were identified as one of the most sensitive populations, and the procedures implemented were designed to protect this group.

Dr. Etzel noted that it was incomplete to only look at outdoor air. She stated that there was a need to consider the kind of exposures that children might have in the indoor environment. Ms. Hultin said that there was no indoor air program in Michigan, and that this had been brought up at the Michigan Asthma Steering Committee. Dr. Gracki added that this might be an example of an area where there was a deficiency.

Dr. DeVito agreed with Dr. Kamrin that it was uncomfortable to say what safety factors should be used, and in what circumstances, as that was a policy decision. However, he concurred that decisions sometimes need to be made with incomplete data sets. Choosing the exact numbers for the safety factors is difficult; however, determining the data gaps and areas of uncertainty is not. Mr. Harrison noted that it was important to state when determinations of uncertainty factors were not science-based decisions. Dr. DeVito added that new approaches to uncertainty were multiple factors with numbers other than 10. This could give a more accurate description of the uncertainty.

Dr. Gracki mentioned the example of mercury. When people became aware of its extreme toxic effects, it was decided that any detectable levels would not be allowed. The exact percentages were not important. Dr. DeVito said that many chemicals were regulated in a similar manner. Dioxin is one compound that is dangerous at levels that are currently undetectable. However, the sensitivity of measuring devices is constantly increasing. Mercury is now measured in picograms rather than micrograms.

Dr. Weil stated that one problem with indoor ambient air was the lack of regulation regarding the home use of insecticides, herbicides, and other toxic compounds. For example, after cleaning a rug with solvent, the air at adult height might be safe within 24 hours. However, the air at the infant's level can remain toxic for a week. While this concerns policy, regulations regarding the sale of toxic products used in the home might be needed. Dr. DeVito stated that if exposure assessments of toxics such as insecticides did not include the major route of exposure, this was a deficiency that could be highlighted. Dr. Kamrin added that data were available from indoor air measurements that could identify specific chemicals that would be of most concern.

VII. PANEL ASSIGNMENTS

Mr. Harrison noted that more literature would be distributed to the Panel. The members would need to read and then begin individual evaluations of the material. More specific assignments would be made at a later date.

VIII. NEXT MEETING DATE

Mr. Harrison stated that the Panel members would be contacted if another meeting was needed to discuss additional information received.

IX. ADJOURNMENT

The meeting was adjourned at 12:41 p.m.

Respectfully submitted,
Keith G. Harrison, M.A., R.S., Cert. Ecol.
Executive Director
Michigan Environmental Science Board